November 29, 2004

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry and Food and Drug Administration Staff:
Hospital Bed System Dimensional Guidance to Reduce Entrapment
[Docket No. 2004D-0343]

Ladies and Gentlemen:

The Indiana Medical Device Manufacturers Council ("IMDMC") appreciates this opportunity to comment on the Draft Hospital Bed System Dimensional Guidance to Reduce Entrapment (the "Dimensional Guidance"). In addition to being interested in the Dimensional Guidance itself, the IMDMC has long had an interest in the process through which FDA develops guidance documents. In the mid-1990s, IMDMC filed a citizens petition with FDA requesting improvements in the guidance process. Our association worked collaboratively with FDA to identify the needed improvements to the guidance process, and ultimately the principles that we developed together were embodied in legislation and regulation in the form of Good Guidance Practices ("GGPs").

The IMDMC is an association of approximately 60 companies—large and small—that either manufacture medical devices or supply goods and services to those who do. Our association includes at least one company that makes hospital beds that would be directly impacted by the draft guidance, and all of our members are impacted by the guidance process that FDA employs.

Based on our review of the information available on FDA's web site, we are writing these comments because we are concerned that FDA has strayed from GGPs in its handling of the Dimensional Guidance. In particular, we are concerned that FDA: (1) separated the Dimensional Guidance from the guidance on test methodology for determining compliance with those dimensions; and (2) delegated the further development of that test methodology to a private group. In this letter, we will explain the background behind and the nature of those concerns.

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I. Factual Background

Because we are not reacting to merely the words on the page of the draft guidance, before we explain our concerns, it is important for us to describe our understanding of the facts leading up to the issuance of the Dimensional Guidance separately from the guidance on test methodology for determining compliance with the dimensions.

The Dimensional Guidance was developed through a very novel process that utilized a working group comprised of representatives of numerous government agencies and outside stakeholders, including manufacturers and providers. FDA was instrumental in the formation of that group – called the Hospital Bed Safety Workgroup or HBSW – in 1999. Furthermore, in many ways, FDA acted as the administrator of the HBSW, for example, by taking responsibility for posting the HBSW's documents on a special page on the Agency's web site. Among other things, the Agency posted minutes from HBSW meetings.

Through much of the years 2000 and 2001, the HBSW worked on developing a guidance document that set forth the dimensional requirements for the safety of rails and the test methodology for assessing whether a given bed conformed to those dimensional requirements. In addition, the group developed clinical guidelines for exercising judgments about when bed rails are appropriate, and an actual tool kit that could be used to assess a given bed's compliance. The group planned to make the tool kit available through a nonprofit organization, ECRI.

During the discussion in various HBSW meetings, the group outlined its thinking on how the guidance would proceed.

For example, in the October 2000 minutes, Dr. Joseph of FDA described the meaning of guidance and the difference between level 1 and level 2 guidance. Dr. Joseph indicated that FDA would welcome the development of the draft guidance by the HBSW to encourage consistency among regulatory bodies. And as described above, the group did in fact draft a guidance setting forth the dimensional requirements and the methods for assessing conformance to those dimensions.

The March 28, 2001, minutes reported that the dimensional recommendations were put in GGP format and were to be submitted to FDA. The appendix to those minutes projected the time frames for publication and review of the guidance. From talking to people involved at the time, it is clear that the document still included both the dimensional and assessment topics.

In the November 1, 2001, meeting, Dr. Joseph observed that the guidance document would probably qualify as a level 1 document under the Agency's GGPs. Indeed, according to the minutes, Dr. Joseph indicated "that she was confident that the agency would choose to process our document as a level 1." At that same meeting, Pat Cricenti of FDA reported that the "dimensional and assessment guidance" is currently making its

way through the FDA approval process. She indicated that it was uncertain when it would be published.

Problems developed, however. Progress ground to a halt. From the web site and from our conversations with those involved, we are not able to piece together all of the reasons for the delay. It appears, though, at least some of the delay was the result of difficulties in finishing an assessment tool that could effectively and reliably determine compliance with the dimensional guidance. Indeed, we understand that work in that area continues even today.

Perhaps out of frustration with the delays inherent in working through this large committee and in doing the validation testing necessary to complete the work, FDA proposed a guidance that was only half done.

On August 30, 2004, FDA proceeded with its new plan and published a notice in the *Federal Register* announcing the availability of the draft Dimensional Guidance.[1] Confounding matters, FDA stated its intention to solicit comment on the second part of the guidance only from the HBSW, not from the public at large.

In a November 23 email to the Issue Group 3, 4 and 5, the FDA Hospital Bed Team justified its position as follows:

- Multiple attempts by the HBSW to finalize the test protocol and tools resulted in extensive time delays in releasing any information on gap size. FDA was repeatedly asked for its guidance over a three year period by health care practitioners and other stakeholders.
- Definition of the testing tool as a medical device itself prohibits FDA from endorsing such a tool in its guidance. Further, had FDA included test tools in the guidance, the manufacturer of the testing tool would need to adhere to the FDA requirements for medical device manufacturers. As a result, the HBSW IG 3, 4, 5 decided to develop a general use testing tool that would be used on other consumer products in order for ECRI to manufacture the kit.

- FDA felt assured that the HBSW IG 3, 4, 5 would prepare a valid testing procedure and tool by the time the guidance would be ready in final form.

As explained below, we take a different view.

[1] 69 Fed. Reg. 52907, *Draft Guidance for Industry and Food and Drug Administration Staff; Hospital Bed System Dimensional Guidance to Reduce Entrapment; Availability* (Aug. 30, 2004).

II. Legal Background

As you know, section 701(h)(1)(C) of the Federal Food, Drug and Cosmetic Act ("FDCA") requires the Secretary to ensure public participation prior to implementation of guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues.

Implementing that statutory directive, FDA's regulations specify what have become known as the Agency's GGPs. Three aspects of those GGPs are important here.

First, GGPs are mandatory. The regulations ***require*** the Agency to follow GGPs when developing a guidance document. In particular, 21 C.F.R. § 10.115(e) explains: "These GGPs must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad audience."

Second, as already observed in the minutes from the HBSW meetings, it seems that this guidance must be developed as a "level 1 guidance." Under the regulations, a level 1 guidance document includes those that meet the statutory test set forth in section 701(h)(1)(C) of the FDCA, described above.[2] The Dimensional Guidance clearly contains new requirements not previously found in FDA law, and therefore must indeed be treated as level 1 guidance.

And third, for level 1 guidance documents, the regulations specify the steps the Agency must follow. The steps include requirements such as: publishing a notice in the *Federal Register*, announcing that a draft is available, posting the draft on the Agency's web site, and inviting comment.[3]

III. Comments

Based upon our understanding of the facts and the law, IMDMC has concerns both with the substance of the draft guidance document and with the process through which the guidance document is being developed. We will separate our comments into those two categories.

A. Substantive

Our concern with what the guidance document says stems from this quandary: We don't know whether this type of standard will be appropriate if we don't know whether a validated tool to measure compliance is even possible. Clearly we would argue that the dimensional requirements are not the appropriate ***type*** of requirements if in fact it turns

[2] 21 C.F.R. § 10.115(c).

[3] 21 C.F.R. § 10.115(g).

out that it is difficult, if not impossible, to develop a validated tool for measuring beds against that ***type*** of dimensional requirement. As the HBSW discussions suggest, it is terribly important for the public health purpose of this project that a validated tool be available to implement the dimensional criteria. Without a standardized, validated tool, our comfort level that the standards will prove effective at their public health purpose is quite low.

Even if we knew that a tool was conceptually possible and practical, we don't know if these are the right ***level*** of requirements until we know what test methods the Agency will employ. The standards and the test methods for measuring compliance with the standards are integrally intertwined. A very high standard can be quite appropriate and acceptable if the test methods for determining conformance to the standard are practical. On the other hand, where the test methodology itself insists on a very high level of confidence, the standard that has to be met can affordably be lower. The two factors are inversely related. Where the test methodology is very rigorous and instills a lot of confidence, less margin for error needs to be built into the standard itself. We really cannot comment on one if we don't know the other.

These really are two different observations. The first one simply relates to whether or not the overall approach of the standard (that is, the ***type*** of standard) can be feasibly implemented, while the second comment relates to the trade-offs that can and should take place between the ***level*** of the standard and the certainty of the assessment technique.

B. Procedural

Quite apart from our concern with what the guidance document itself says, we are concerned about the process FDA is using to develop this guidance document. With respect to that process, we have two separate concerns.

1. We Have Been Denied Our Opportunity to Comment Effectively.

That may seem like a strange title for a section of a comment letter. But as you can tell from our comment on the substance of the guidance, we believe is impossible to comment insightfully when the guidance is being released piecemeal. The Dimensional Guidance identifies certain standards that bed rails will have to meet, but fails to provide critical information about how compliance with those standards would be evaluated. Specifically, again as already noted, the guidance does not identify the techniques for measuring the dimensions of the bed to assess whether the bed meets the proposed standards. It is the measurement techniques that are by far the most intellectually challenging and controversial.

Separating the two topics deprives us of our right to comment on the guidance document as a whole and to comment appropriately on either part. That we have that right to comment is clear from the regulations implementing the GGPs. Additionally, the purpose of the opportunity to comment is the same for guidance as it is for rulemaking; therefore, we look to case law on rulemaking for instruction.

A notice of proposed rulemaking must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.[4] In particular, although an agency, in its notice of proposed rulemaking, need not identify precisely every potential regulatory change, its notice must be sufficiently descriptive to provide interested parties with fair opportunity to comment and to participate in rule making.[5] That notice, or information subsequently supplied to public, must disclose in detail the thinking that has animated the form of the proposed rule and data upon which it was based.[6]

Where a rule has multiple components that impact each other, the agency must pull those components together in its proposal so that their interconnections are apparent. For example, a court found that the Environmental Protection Agency did not provide adequate notice and opportunity for comment on its emissions standard requiring industrial furnaces not having a bypass duct (i.e., wet kilns) to meet an alternative total hydrocarbon ("THC") limit.[7] The EPA's proposed limit sought to ensure that flue gas hydrocarbon ("HC") and carbon monoxide ("CO") concentrations when burning hazardous waste fuels are not greater than when not burning hazardous waste. But nowhere in proposed rule did EPA indicate it was contemplating the possibility of dual CO and THC baselines. The court held that the component parts of EPA's proposed standards were never collected together in such fashion as to enable parties to anticipate and adequately comment on the ultimate standard.

The Third Circuit U.S. Court of Appeals has confronted the issue presented by the hospital bed safety guidance in a case with eerie similarity. In *Wagner Elec. Corp. v. Volpe*,[8] the National Highway Traffic Safety Administration wanted to adopt a standard developed by an outside body (the Society of Automotive Engineers). The standard, which addressed the adequacy of turn signals, had two parts: (1) performance criteria, and (2) testing procedures to determine whether the criteria were met. The agency failed to solicit comment on both aspects of the standard, and the court rejected the final rule and required the agency to redo the rulemaking. In doing so, the court noted that the

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[4] *Florida Power & Light Co. v. U.S.*, 846 F.2d 765 (D.C. Cir., 1988); *Cat Run Coal Co. v. Babbitt*, 932 F.Supp. 772 (S.D.W.Va., 1996).

[5] *Chocolate Mfrs. Ass'n of U.S. v. Block*, 755 F.2d 1098 (4th Cir., 1985); *see also American Medical Ass'n v. Reno*, 57 F.3d 1129 (C.A.D.C., 1995).

[6] *Home Box Office, Inc. v. F.C.C.*, 567 F.2d 9 (D.C. Cir., 1977).

[7] *Horsehead Resource Development Co., Inc. v. Browner*, 16 F.3d 1246 (D.C. Cir., 1994).

[8] 466 F.2d 1013 (3rd Cir., 1972)

standard—including both the performance criteria and the testing methods—was developed by the Society as an integrated whole, and that the public could not comment effectively on just one part of the standard. For example, if the agency proposes to make the test methods more demanding, a commenter might wish to suggest that the performance criteria be lowered.

The Dimensional Guidance presents the exact same issue. The HBSW developed an integrated policy that spelled out dimensional guidance and assessment guidelines

together. Indeed, the meeting minutes chronicle the development of a single set of guidelines covering both aspects throughout years 2000 and 2001. By choosing to separate those topics and only publish the Dimensional Guidance, FDA is depriving us of our opportunity to comment on the substance of the guidance. That's not right.

2. FDA Cannot Limit the Opportunity for Comment to Only the HBSW.

Larry Kessler's August 17 note to the HBSW members seems to suggest that the test methods themselves will not be vetted beyond the work group itself. At least it states no intention to go beyond that group with regard to that aspect of the guidance. If that is indeed the case, FDA needs to reconsider its approach.

As explained above, the test methods are every bit as important to the overall regulatory approach as the standards that must be met. There is no reason we can think of for treating them differently. They are complex, they directly impact the determination of whether a bed is in compliance, there is judgment and much knowledge required in setting them, they are controversial, and they are conceptually intertwined with the standards themselves that have been vetted. The difficulty the work group has had in arriving at methods that can be validated demonstrates the complexity of the task. In fact, it seems to us the test methods must be contained in a level I guidance and vetted through the Federal Register just like the standards were.

Comment by a select group is no substitute for the more general solicitation of comments required under the GGPs. Limiting the opportunity to comment to only the organizations that comprise the HBWG, or who know someone on the committee, is not the American way. Commenting is supposed to be truly open, not just available to those who are "in the know" or who have good contacts. There may be many patient groups, providers, manufacturers and others not on the work group who have useful comments to make. It's not up to the agency to decide who gets to comment.

IV. FDA's Justifications Do Not Change These Concerns

- First, the ends do not justify the means. We understand that FDA is frustrated by the delay; we are too. But there are still rules that govern how guidance is developed, and FDA did not follow those rules.

- Second, we simply do not understand FDA's arguments about the tool being a medical device.

  - In looking at the definition of a device, while we assume that FDA must consider this to be an accessory to a medical device, we do not see it that way. Generally equipment designed to test a medical device is not itself deemed to be a medical device, particularly where it has applications outside of medicine.
  - More importantly, we do not see the link between including the tool in the guidance and a manufacture's obligation to meet the medical device requirements. The tool either is or is not a medical device and the requirements either do, or do not, apply, regardless of whether the product is discussed in a guidance document.
  - And finally, FDA's concern about endorsing a device makes no sense to us. Hardly a week goes by when FDA doesn't issue or revise a guidance document that describes a product generically and the parameters that it must meet. The agency does so without endorsing a proprietary brand of product at issue. The guidance simply describes generic parameters that such products must meet. FDA could easily write a guidance which describes generically the parameters that the tool must meet without endorsing any particular firm's version of the device. Taking that approach would create the opportunity to obtain the feedback that we observed above is necessary.

- Third, FDA's final justification, that the testing procedure and tool would be completed by the time the guidance is put in final form, simply misses the point. Our point, made above, is that we do not have a meaningful opportunity to comment without the test methods and tool description being included in the proposal. The fact that the tool might be ready for use later does not help us comment at all, nor does it reassure us that the tool approach is even possible.

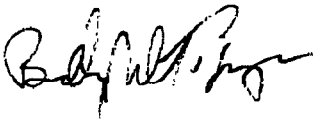
V. Conclusion

FDA needs to reconsider its options. One option would be for the agency, after the test methods have been validated, to start this comment period over and include in its proposal both the dimensional criteria and the assessment techniques for measuring compliance. We understand that the validation is taking longer than FDA would like, and all of our members understand the frustration of waiting for validations to be completed. But such delays do not justify acting rashly and proceeding before the work is done.

The Agency and the HBSW have done a good job of raising the bed rail safety issue and galvanizing action. Obviously any steps that can be taken to move the validation along should be taken, but until it is complete, we would encourage the Agency to be patient in moving the guidance forward. The Dimensional Guidance should not be put in final form until the assessment technique guidance has been vetted, and when vetting that guidance the agency should be willing to accept comments on both.

We appreciate this opportunity to offer comments, and will be happy to help the Agency any way we can.

Very truly yours,



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